VALENT BIOSCIENCES®

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I034868

Update of I034120

February 23, 2022

By Pesticide Submissions Portal in Central Data Exchange

Document Processing Desk – 6(a)(2)
Office of Pesticide Programs – 7504P
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Information Submitted under FIFRA § 6(a)(2)
Valent BioSciences LLC, EPA Company No. 73049
VectoBac® 12AS Biological Larvicide, EPA Reg. No. 73049-38

Dear Sir or Madam:

-001 On May 25, 2021, Valent BioSciences LLC (VBC) submitted an April 26, 2021 claim by the Massachusetts Department of Agriculture Resources (MDAR) that samples of VectoBac® 12AS Biological Larvicide, EPA Reg. No. 73049-38 (Product), taken by MDAR and analyzed by the Massachusetts Department of Environmental Protection (MDEP) were potentially contaminated with per- and polyfluoroalkyl substances (PFAS). VBC submitted MDAR's claim to EPA under FIFRA § 6(a)(2), as information about previously unknown contamination of Product, in accordance with 40 C.F.R. § 159.179(b).

Since May 25, 2021, VBC has obtained new information indicating that the samples of Product collected by MDAR and analyzed by MDEP are not and were never contaminated with a specific PFAS, namely, perfluorooctanesulfonic acid (PFOS). The new information is as follows.

VBC's May 25, 2021 report to EPA says that MDEP detected PFOS in Product samples at concentrations ranging from 2,320 to 5,040 ng/L. VBC can now explain the PFOS contamination allegedly observed by MDEP. By high-resolution mass spectrometry, VBC has discovered that the "PFOS" contamination is something else: interference caused by a bile salt, taurochenodeoxycholic acid, that is a component of Product.

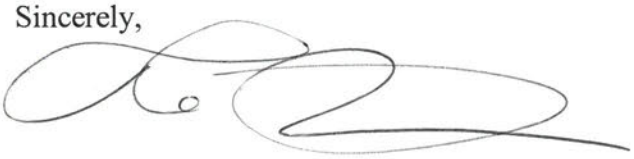
The results of VBC's new analysis are documented in the attached, unpublished study report. The report also explains why MDEP's analysis of Product samples using low-resolution mass spectrometry and EPA Method 533 was unable to distinguish between contamination with PFOS and interference caused by a bile salt component.

In a meeting with MDEP on February 11, 2022, VBC presented the attached study results to MDEP, who welcomed the new information and expressed an intent to perform their own, confirmatory analysis. Meanwhile, however, VBC's new study shows that Product is not contaminated with PFOS and instead contains a bile salt component that resembles PFOS in low-resolution mass spectrometry using EPA Method 533.

In conclusion, there is no longer any reliable evidence that Product samples taken by MDAR and analyzed by MDEP are or were ever contaminated with PFOS, and there is no longer any contamination of Product with PFOS that is reportable to EPA under 40 C.F.R. § 159.179(b).

If you have any question about this submission, please contact me by email at maria.herrero@valentbiosciences.com or by telephone at (847) 968-4725. Thank you.

Sincerely,



Maria Pilar Herrero
Regulatory Manager

MPH/mb

Attachments:

Attachment A January 15, 2022 unpublished study report (5 pp.) – **Contains Confidential Manufacturing Process Information Protected from Disclosure by FIFRA § 10(d)(1)(A), 7 U.S.C. § 136h(d)(1)(A)**

Attachment B January 15, 2022 unpublished study report (5 pp.) – sanitized public copy that contains no confidential business information

(b)(4) – Claimed Confidential Business Information – Pages 3-7 (Attachment A)